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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/301,842	04/29/1999	BRIAN C.A. FERNANDES	P0008383.00	6147

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MEDTRONIC, INC.
710 MEDTRONIC PARKWAY NE
MINNEAPOLIS, MN 55432-9924

EXAMINER	
LAM, ANN Y	

ART UNIT	PAPER NUMBER
1641	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/301,842	FERNANDES ET AL.	
	Examiner	Art Unit	
	ANN Y. LAM	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 October 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-36,41-69,76 and 77* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-36,41-69,76 and 77* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/20/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

Claim 21 is objected to because of the following informalities: in claim 21, line 2, "(col. 32, line 8". Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1. Claims 21-30, 32-36, 41-69 and 76-77 are rejected under 35 U.S.C. 103(a) as being unpatentable over Helmus et al., 5,447,724, in view of Tweden et al., 5,895,419, and further in view of Fearnot et al., 5,609,629.

Applicant claims a heart valve prosthesis comprising a sewing ring comprising an annular support initially formed from a biostable polymer mixed with a therapeutic agent, said annular support overlaid by a polyester fabric overlay, wherein said annular support provides at least one therapeutic effect to the fabric overlayer.

Helmus disclose polymers which may be used in the formation of or the coating of medical devices which contact body various body tissues and bodily fluids such

device being for example, artificial heart components, vascular grafts, heart valves among other things (col. 9, lines 52-68.)

It is also taught by Helmus that the articles might also be formed entirely from the release polymer, in which case, a prepolymer mixture including the desired quantity of heparin is prepared, formed into the desired shape and polymerized. A prepolymer solution containing an elutable component is next applied over the article and polymerized to form the surface-layer. Additionally, articles may be formed by thermal means such as injection molding a mixture of polymer and active agent. The outer layer may be formed by molding the polymer and elutable agent mixture around the body of the device by insert molding techniques (col. 9, lines 38-49.)

Thus, as to claims 21, 45, 46, 52 and 60, Helmus discloses an implantable medical device (see column 9, lines 52-68, disclosing a medical device such as artificial heart components) initially formed from a biostable polymer mixed with a therapeutic agent (see col. 9, lines 38-49, disclosing that the medical device/article may be formed from a prepolymer mixture including the desired quantity of heparin is prepared or alternatively by injection modling a mixture of polymer and active agent), and wherein the medical device comprises a body portion overlaid by a fabric overlayer (see column 9, lines 38-48, disclosing a prepolymer solution containing an elutable component applied over the article and polymerized to form the surface-layer, or alternatively injection molding a mixture of polymer and elutable agent mixture around the body of the device by insert molding techniques), and wherein medical device provides at least one therapeutic effect to the fabric overlayer (see col. 9, 39-40, line

45-46, disclosing the therapeutic agent and col. 3, lines 34-47, and col. 6, lines 18-25, disclosing release of the therapeutic agent.)

However, Helmus does not specifically disclose an embodiment wherein such a medical device is annular or that the medical device includes a polyester fabric overlayer.

Tweden discloses an annuloplasty ring (22) that includes an outer layer of fabric (24), such as a woven or knitted polyester, which may surround a frame (23), which may be flexible, and a polymer, such as silicone (see column 2, lines 45-50, and see column 3, lines 30-33.) Tweden also discloses that the devices could be coated with a therapeutic agent, (see column 2, lines 51-67, see also col. 3, lines 16-19, and col. 4, lines 20-22).

Specifically, Tweden teach that the valved grafts are coated with different pre-clotting agents, such as collagen or gelatin. In this application, the silver coating may underlie the pre-clotting agent, and it is contemplated that silver treatment of only the cuff may be desired in some applications (col. 3, lines 6-28.) It is disclosed that coating portions of cardiovascular prostheses with a thin adherent film of silver provides protection from infection of the device. In some instances, the entire fabric member of the prosthetic device may not be coated with the silver, such as in areas of suture markings. In addition, in vivo experiments have shown excellent tissue ingrowth, without excessive thrombus formation. Minimal migration of silver into surrounding tissue may provide further anti-microbial protection. See column 4, lines 23-31.

Since Helmus discloses that the prepolymer mixture can be used to form various medical device such as artificial heart components and heart valves (col. 9, lines 52-68), the skilled artisan would have looked to the art, such as the Tweden patent, for such specific medical devices that can be formed according to the Helmus teachings. It would have been obvious to one of ordinary skill in the art to combine the teachings of Helmus and Tweden regarding elements of a heart valve prosthesis that provide desirable therapeutic effects. In combining the teachings of Helmus and Tweden, it would have been obvious to the skilled artisan that the Tweden heart valve can be formed such that the body of the heart valve can be formed according to Helmus, that is including therapeutic materials, and can include a fabric overlayer as taught by Tweden, including a coating of a therapeutic agent which is specifically suggested by Tweden. The skilled artisan would have recognized that forming the heart valve from elements taught by Helmus and Tweden result in a heart valve with structural elements that provide therapeutic effects as taught by Helmus and Tweden. The skilled artisan would have reasonable expectation of success since Helmus teach that the disclosed invention can be used to form medical devices such as artificial heart components, vascular grafts, heart valves among other things (col. 9, lines 52-68), which the skilled artisan would recognize as encompassing annuloplasty rings, such as those disclosed by Tweden. (The Tweden annuloplasty ring meets the annular limitation recited by Applicant.) Moreover, the teachings of Helmus and Tweden are compatible with each other, since Helmus teach using a therapeutic agent in the polymer body and/or coating (col. 9, lines 38-49), and Tweden al. also teach that the underlying polymer

body can be treated with a pre-clotting agent (col. 3, lines 6-28), and that the body may include a silver coating for protection from infection, or may not be coated with the silver (col. 4, lines 23-31), in which case, it is understood that the polymer body may still include the coating of pre-clotting agent. Thus, it is clear to the skilled artisan that the device can be formed in various ways, including one in which the body is a polymer including a therapeutic agent (e.g., formed of the therapeutic agent, as taught by Helmus, or coated with the therapeutic agent, as taught by both Helmus and Tweden et al.), and overlaid with the fabric, for example, in portions of the polymer body, wherein the fabric may or may not include a silver coating for protection from infection, as taught by Tweden et al.

Also, as to claims 21, 23, 27, 32, 33, 43, 50, 51, 54, 58, 67-69, while Helmus discloses that the therapeutic agent comprises an anti-inflammatory agent (see column 2, line 6), Helmus does not disclose the anti-inflammatory agent as being dexamethasone.

However, Fearnot teaches that dexamethasone or other anti-inflammatory agent can be coated on an implantable medical device for implantation into, for example, the vascular system (column 4, line 33) for delivery of the agent (col. 8, lines 46-47 and col. 8, line 66 – col. 9, line 2.) It would have been obvious to one of ordinary skill in the art at the time the invention was made, to apply a layer of dexamethasone, as taught by Fearnot, onto implantable medical devices as taught by Helmus-in-view-of-Tweden, since dexamethasone, being an anti-inflammatory, is disclosed by Fearnot as being a useful bioactive agent to be coated on an implantable medical device.

As to claims 34, 44 and 69, Helmus teaches that the therapeutic agent may be chosen from a variety of agents, such as antimicrobial agents as well as antiproliferative agents such as heparin (col. 2, lines 1-8.) However, there does not appear to be a disclosure of forming the polymeric body using more than one therapeutic agent. However, using a combination of agents, especially where both types are disclosed as being useful in the prosthetic medical device, would have been obvious to the skilled artisan since the skilled artisan would have recognized that the device would have the desirable benefits of both therapeutic agents. The skilled artisan would have reasonable expectation of success in incorporating two different types of therapeutic agents as he would one type of therapeutic agent into the polymeric body using the methods disclosed by Helmus.

As to the following claims, Tweden discloses the limitations as follows.

As to claims 22, 30, 42, 47, 63, the polymer insert comprises silicone, see column 3, line 36-38.

As to claims 24, 28, 35, 36, Tweden discloses that the heart valve may be bioprosthetic or mechanical, see column 2, lines 3-6, and lines 30-35.

As to claims 25, 53, 57, 66, Tweden teaches a fabric of polyester, see column 2, lines 45-50, and see column 3, lines 30-33.

As to claims 26, 48, 49, 64, 65, the body portion additionally comprises a metal, see column 3, line 40.

As to claims 29, 60, 61,62, Tweden discloses that the heart valve comprises a polymer insert containing struts attached to tissue leaflets to form a valve housing,

wherein a fabric sheath encloses the polymer insert to form sewing ring, see column 2, line 31.

As to claims 41, 56, Tweden discloses an annuloplasty ring (22). Also, as to claim 41, Tweden discloses the suture/sewing cuff or fabric as comprising a knitted or woven fabric of polyester (see column 2, lines 45-50, and see column 3, lines 30-33.) In combining the teachings of Tweden and Helmus as discussed above, the skilled artisan would utilize a prepolymers mixture to form a polymer (with therapeutic agent) such as polyester as disclosed by Tweden as the particular type of polymer in the Helmus invention.

As to claim 55, use of the device described above provides the same properties as claimed because the device has the same structural elements and therefore has the same properties.

As to claim 59, because the combination of the prior art as discussed above would result in the same invention as claimed by Applicant, it must have the same biological effect recited by Applicant.

As to claims 76 and 77, Applicant recites an anuloplasty ring or method of making a medical sewing ring *consisting of* the body or annular insert formed from a therapeutic agent with the polymer, enclosed in a fabric sheath, and wherein the agent provides a therapeutic effect to the sheath. The discussion of claim 21 above is equally applicable here since, as mentioned above, the skilled artisan would have recognized that the device can be formed in various ways, including one in which the body is a polymer including a therapeutic agent (e.g., formed of the therapeutic agent, as taught

by Helmus, or coated with the therapeutic agent, as taught by both Helmus and Tweden et al.), and overlaid with the fabric, for example, in portions of the polymer body, wherein the fabric may or may not include a silver coating for protection from infection, as taught by Tweden et al. Thus, such embodiments encompass a ring structure consisting of the body or annular insert formed from the therapeutic agent with the polymer, enclosed in a fabric sheath. The therapeutic agent inherently provides a therapeutic effect to the sheath.

2. Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Helmus et al., 5,447,724, in view of Tweden et al., 5,895,419, and Fearnot et al., 5,609,629, as applied to claim 30 above, and further in view of Myers, 5,716,397.

Helmus, Tweden and Fearnot have been discussed above. It is noted that Tweden discloses an annuloplasty ring (22). However, neither Helmus nor Tweden does not disclose a polymer insert comprising radiopaque flexible silicone rubber.

Myers discloses an annuloplasty ring consisting of a soft core of silicone rubber impregnated with radiopaque salt (col. 1, lines 44-51 and col. 2, lines 46-50.) Myers teaches that it is desirable for the annuloplasty ring to be flexible once implanted (col. 2, 7-10.) The radiopacity allows the presence and functioning of the implant to be monitored after completion of the implant surgery (col. 2, lines 50-53.)

It would have been obvious to one of ordinary skill in the art combine the teachings of Helmus, Tweden and Myers such that the mixture of polymer (or prepolymer) with therapeutic agent also comprises silicone rubber and a radiopaque agent to form an annuloplasty ring that provides the benefit of flexibility and radiopacity for monitoring after implant surgery, as taught by Myers.

Response to Arguments

Applicant's arguments have been considered but are not persuasive.

Applicant argues that Helmus requires use of an overlayer of an elutable agent to control release of the agent. This argument appears to imply that combination with the teachings of Tweden would result in a device without an overlayer of an elutable therapetic agent. This is not persuasive as Tweden teach that the fabric may be overlaid with a silver coating, which provides a therapeutic effect of protection from infection, and thus providing such a coating is compatible with the Helmus teachings of using a therapeutic agents on the device. As mentioned in the grounds for rejection, given the teachings of Helmus and Tweden, it is clear to the skilled artisan that the device can be formed in various ways, including one in which the body is a polymer including a therapeutic agent (e.g., formed of the therapeutic agent, as taught by Helmus, or coated with the therapeutic agent, as taught by both Helmus and Tweden et al.), and overlaid with the fabric, for example, in portions of the polymer body, wherein the fabric may or may not include a silver coating for protection from infection, as taught by Tweden et al. Even providing a device in which portions of the fabric are not coated with a silver

coating is not necessarily incompatible with the Helmus teachings. To the contrary, the skilled artisan would look to *both* teachings for how a medical device can be formed, and it is specifically taught by Tweden that it may not be necessary to provide a silver coating on all parts of the device.

As to newly added claims 76 and 77, they have been addressed above.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Chapman, 4,348,329, disclose use of anti-inflammatory steroids as a surface of prosthesis such as heart valves for release of the composition.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANN Y. LAM whose telephone number is (571)272-0822. The examiner can normally be reached on Mon.-Fri. 10-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on 571-272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ann Y. Lam/
Primary Examiner, Art Unit 1641